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How should vaccination services be planned, organized, and managed? Results from a survey on the Italian vaccination services

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Parole chiave: Servizio vaccinale, standard, gestione, copertura vaccinale, prestazione, valutazione qualità

Abstract

Background. *Quality improvement is an increasingly recognized approach to maximize service effectiveness and minimize costs in public health. However, the Italian law never provided for the institutional accreditation of vaccination services. Furthermore, a recently approved law added six more compulsory vaccinations to the original four, which has led to a considerable increase in vaccination efforts, without any previous resources evaluation. The aim of the study was to investigate structural, organizational and managerial characteristics of the Italian vaccination services, in order to suggest the adoption of adequate quality standards.*

Study design. *A survey involving the representatives of the Italian Regions and Autonomous Provinces was performed between September 2017 and September 2018.*

Methods. *An online questionnaire, including 26 items, designed to evaluate the structural, organizational and managerial characteristics of vaccination services was administered. The correlation between the number of vaccination centres and the coverage for each region was used to evaluate the performance of the vaccination services.*

Results. *Respondents from seven Regions, totaling >15,000,000 inhabitants, answered the questionnaire. Overall, each vaccination service was potentially accessed by an average of 519 children aged zero to 24 months, with a β-coefficient of -0.87 ($p = 0.01$) for infant vaccination coverage in 2016. Eighty-five percent of vaccination services were provided with architectural features to accommodate the disabled but only 49% provided reserved parking lots. An average of 0.4 physicians and 0.6 other healthcare workers per 10,000 inhabitants were employed in vaccination services, with complete computerization in 74% of them.*

Conclusions. *The inverse relation between vaccination services' spatial accessibility and vaccination coverage suggests that distance and accessibility of vaccination services should be considered in planning. This survey constitutes a baseline data for Italian vaccination services that could be useful for decision makers in establishing minimum requirements to provide high-quality preventive healthcare services.*

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Introduction

Quality improvement has been an increasingly recognized approach to maximize service effectiveness and minimize costs in Public Health. A recent review selected five efficiency and eight effectiveness measures to define and assess quality improvement outcomes in Public Health (1).

The need to control health procedures and standardize healthcare facilities in the 20th century led to the foundation of the first accreditation institute, in the United States: the Joint Commission on Accreditation of Hospitals (2). However, quality improvement is still insufficiently implemented in vaccination services, with the exception of the United States, where the National Vaccine Advisory Committee already produced a draft of standards for vaccination services in the late 1980s. Some of these standards are relevant today for improving the quality of vaccination services: being open in the afternoon and on weekends, cost-free vaccinations, standardized procedures and availability of Health Care Workers (HCWs) to provide timely and complete information to vaccination service users (3).

Since the '90s, Italy has witnessed a legislative proliferation in the field of institutional accreditation. The law defines institutional accreditation as the procedure by which an authority or institution (eg the State or the Regional Administrations) recognizes other institutions' possession of specific requirements (qualification standards), whose possession allows the institution to be selected to work for the Italian Health Service (4–6). However, these laws do not include institutional accreditation for preventive healthcare and vaccination services. Definition of the structural, organizational, and management standards of vaccination services must be a goal for public health scientific organizations.

Despite the lack of legislation on institutional accreditation, experiments with accreditation models were conducted in some Italian Regions to develop accreditation manuals for vaccination services. An expert commission in Region Abruzzo identified 56 requirements. These requirements were evaluated by both the HCWs themselves and external observers (7). In addition, in Region Friuli Venezia Giulia an instruction manual that identified 12 standards was developed (8). In both cases, regardless of the scores assessment conformity for each standard, vaccination services were classified as follows: accreditation with excellence, accreditation, *sub judice* accreditation, and refused accreditation.

Furthermore, in Italy, due to a reduction in vaccination coverage rates due to the spreading of vaccination hesitancy a/o refusal and the consequent resurgence of measles outbreaks, a law mandating a 10 compulsory vaccinations schedule (instead of 4) for admission to kindergarten was approved in 2017. This law helped to increase the vaccination coverage but was not preceded by a previous evaluation of the adequacy of vaccination services to respond to the increase in vaccination demand (9).

The aim of this study was to investigate the structural, organizational, and managerial characteristics of Italian vaccination services in order to suggest a minimum set of quality standards to be adopted.

Methods

An online survey was conducted between September 2017 and September 2018 involving the Representatives of Italian Regions and Autonomous Provinces in the Interregional Committee of Prevention. For those Regions whose representatives did not respond, the same questionnaire was submitted to other key vaccination management figures, such as representatives

of the Regional Health Authority, major Local Health Unit Prevention Department, or University.

The questionnaire included 26 questions to evaluate the structural, organizational and managerial characteristics of vaccination services. The variables within the questionnaire were developed considering the previous international experience in health service accreditation (3, 7, 8, 10, 11).

The questionnaire was divided into four sections. The first section included eight questions on the number of vaccination centres and their characteristics (size, equipment, parking, and other facilities). In the second section, 12 questions gathered information on the HCWs working in vaccination centres, business hours, level of planned performance, and established quality controls. The third section investigated the use of information technology (IT) in vaccination services and the types of personnel. The four questions in the last section explored the role of other HCWs in vaccination management, such as general practitioners (GPs), paediatricians, and pharmacists.

To evaluate the vaccination service performance, the correlation between the number of vaccination centres per region and the regional vaccination coverage data for childhood vaccinations pre-Law 119/2017 (the four originally compulsory against diphtheria, tetanus, hepatitis B and poliovirus, plus those recommended against pertussis and *Haemophilus influenzae* type b – the DTP-HBV-IPV-Hib or hexavalent vaccine) and adult anti-influenza vaccinations were calculated using 2016 data (12). The basic theoretical model was that of the European Foundation for Quality Management, whose main aim is to make companies more competitive through total quality management. This dynamic and cyclical model is based on a factors-and-results matrix called RADAR. It starts by determining factors to achieve results and, from the results, produces innovation, which generates knowledge and, then, produces new factors (13).

All data were collected anonymously using a Microsoft Excel spreadsheet and the Pearson correlation analysis was performed using Stata v. 14.2 software with a 95% confidence interval.

Results

The survey was finally performed on 7 out of 20 Italian Regions or Autonomous Provinces involved (35%), covering a total population of over 15,000,000 (a quarter of the Italian population). The Regions were geographically distributed throughout Italy, with one in the northwest, two in the northeast, one in central Italy, and three in the south.

Table 1 reports the results of context analysis of the Regions surveyed, including the number of vaccination services centres and the number of people with potential access to them. In 2016, each vaccination service was potentially accessed by an average of 519 children aged zero to 24 months, with a range of 287 to 987. During the same time, the mean DTP-HBV-IPV-Hib vaccination coverage in all Regions was 91.2%, with a regional β-coefficient of -0.87 ($p = 0.01$). In 2016, each vaccination service was accessed by an average of 6,775 adults over the age of 65 years, with a range of 3,899 to 9,682. The mean anti-influenza vaccination coverage was 51.1%, with a regional β-coefficient of -0.72 ($p = 0.07$).

Table 2 shows the structural characteristics of the vaccination services of the seven Regions. An independent waiting room was available in 61% of service centres. In only one Region was there a waiting room for each vaccination service centre and only 45% to 81% of services in the other regions had a waiting room. An emergency kit was

Table 1 - Number of people users per vaccination service and association with vaccination coverage in 2016.

	Number of vaccination services	Number of children 0-24 months per vaccination service	DTP-HBV-IPV-Hib vaccination coverage	β-coefficent	Adults >65 years per vaccination service	Anti-influenza vaccination coverage	β-coefficent
Region 1	11	987	91.2%	-0.87 (p = 0.01)	9,862	51.1%	-0.72 (p = 0.07)
Region 2	45	463			9,195		
Region 3	250	350			4,158		
Region 4	104	314			3,954		
Region 5	223	287			3,889		
Region 6	37	708			8,471		
Region 7	47	521			7,893		
Mean	102	519			6,775		

available in 93% of vaccination services. In five regions, each vaccination service centre had at least one emergency kit, but in one region only 44% of vaccination services had an emergency kit. A total of 85% of vaccination service centres were provided with architectural features to accommodate the disabled, with only two regions ensuring 100% access for the disabled. Reserved parking was available in an average of only 49% of vaccination service centres, with a range of 4% to 84%.

Regarding organizational characteristics (Table 3), vaccination services employed an average of 0.4 physician per 10,000 inhabitants, 56% of them specializing in public

Table 2 - Structural characteristics of vaccination services

Structural characteristics	Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7	Total
Vaccination services with an independent waiting room, n (%)	15 (79%)	45 (100%)	150 (60%)	72 (69%)	100 (45%)	23 (62%)	38 (81%)	443 (61%)
Vaccination rooms per vaccination service, n (mean)	1.4	1	1.1	1.2	1.1	2.2	1.4	1.3
Vaccination services with emergency kit availability, n (%)	19 (100%)	45 (100%)	250 (100%)	46 (44%)	220 (99%)	37 (100%)	47 (100)	664 (93%)
Vaccination services with at least one freezer with continuous temperature detection, n (%)	12 (63%)	45 (100%)	185 (74%)	99 (95%)	180 (81%)	36 (97%)	45 (96%)	602 (84%)
Vaccination services with full abatement of architectural barriers for the disabled, n (%)	19 (100%)	45 (100%)	194 (78%)	86 (83%)	190 (85%)	35 (95%)	41 (87%)	610 (85%)
Vaccination services with reserved parking lots, n (%)	4 (21%)	NA	167 (67%)	26 (25%)	100 (45%)	31 (84%)	2 (4%)	330 (49%)
Other places to administer vaccination yes or no, if yes specify.	GP or peadiatrician office and public events.	NO	NO	GP office and public events	School and migrant centers.	School, migrant centers and hospital	Hospital and home vaccination.	

NA= not available

Table 3 - Organizational characteristics of vaccination services

Organizational characteristic	Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7	Total/Mean
Physicians per 10,000 people, n	0.4	NA	0.4	0.6	0.2	0.3	0.3	0.4
Other healthcare workers per 10,000 people, n	0.8	NA	0.4	0.5	0.8	0.8	0.6	0.6
Physicians specialized in Public Health, n (%)	11 (69%)	NA	10 (5%)	56 (45%)	45 (46%)	29 (72%)	42 (98%)	193 (56%)
Percentage of healthcare workers operating full time in vaccination services, %	0%	NA	NA	16%	40%	80%	54%	38%
Vaccination services open for business on at least one weekday afternoon, n (%)	19 (100%)	21 (45%)	98 (40%)	99 (95%)	43 (19%)	24 (65%)	26 (55%)	330 (49)%
Vaccination services open for business on Saturdays, n (%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)	6 (3%)	NA	6 (13%)	7 (1%)
Percentage of vaccination service with vaccination by appointment, %	100%	100%	100%	66%	19%	100%	98%	80%
Vaccination services plan performance?	Yes	Yes		No	No	Yes	Yes	67%
Do vaccination services have an internal policy for vaccination?	Yes	Yes	Yes	No	Yes	Yes	Yes	86%
Do vaccination services have a periodical quality control?	Yes	Yes	No	No	Yes	No	Yes	57%

NA = not available

health, a proportion that fluctuated between 5% and 98%. Furthermore, vaccination services employed a mean 0.6 other HCWs per 10,000 inhabitants. An average of 49% vaccination services, ranging from 19% to 100%, were open for business on at least one week day afternoon and 1% held Saturday business hours, ranging from zero to 13%. Vaccination services by appointment were available in 80% of vaccination service centres, with four Regions offering 100% of vaccine services by appointment, whereas this figure fluctuated from 19% to 98% in the other Regions.

Table 4 shows the immunization services management characteristics. Vaccination services were paperless in 74% of centres but in only three Regions vaccination services were completely computerized. In 29% of Regions, technical workers managed the IT, but in most regions the IT was handled by the vaccination services' HCWs.

Table 4 - Managerial characteristics of vaccination services

Management characteristics	Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7	Total
Paperless vaccination services, n (%)	19 (100%)	45 (100%)	225 (90%)	9 (9%)	150 (67%)	37 (100%)	47 (100%)	532 (74%)
Technical workers manage informative system?	Yes	No	No	No	Yes	No	No	29%
Are vaccination services equipped with the same informative system?	Yes	No	Yes	Yes	Yes	Yes	Yes	86%
With what frequency are the vaccine reports produced?	6 months		6 months	6 months	3 months	Variable among vaccination services	6 months	

Table 5 - Role of non medical healthcare workers in vaccination services

	Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7
Paediatrician	Infant vaccination involvement	None	None	None	None	None	None
GP	Influenza vaccination involvement	None	Influenza, Pneumococcus and Zoster vaccination involvement	Influenza vaccination involvement	Pneumococcus and Zoster vaccination involvement	Pneumococcus vaccination involvement	Influenza and Pneumococcus Vaccination involvement
Pharmacist	Vaccination supply	None	Farmacovigilance	None	Farmacovigilance and vaccination certification	Vaccination supply	Vaccination supply

Almost all Regions surveyed included other professionals in the management of vaccination (Table 5). Most Regions (86%) involved a GP for anti-influenza, anti-pneumococcus, and anti-zoster vaccinations. Only one Region engaged paediatricians for infant vaccination, while pharmacists were involved more frequently in vaccine supply and pharmacovigilance activities.

Discussion

The definition of vaccination services standards became a key topic only recently (14), although it was already addressed internationally to improve services and increase vaccination coverage (3). In Italy, we are still far from identifying vaccination service standards at a national level, partly because full information is lacking.

Vaccination services are highly heterogeneous in terms of quality and only partially consider their respective population densities, public and private transport systems, and local geography.

This study showed an inverse correlation between DTP-HBV-IPV-Hib vaccination coverage and the potential number of users for each vaccination service centre. Considering the wide range of factors that can determine the percentage of citizens receiving scheduled vaccinations, the low accessibility of vaccination services can play a major role. The inverse relation between the spatial accessibility of vaccination services and vaccination coverage was already assessed in a Canadian study (15) that evaluated the influenza vaccine coverage during the 2009–2010 season in Montreal. That study used a gravity model to show the main factors associated with the fluctuation of vaccination coverage (16). The data suggested that distance and accessibility to vaccination services should be considered during planning. Another study, conducted among children in Washington, DC, showed that those with greater spatial accessibility were more likely to complete their vaccination schedules for each vaccine, where spatial accessibility was a measure of the population-medical personnel rate (11).

Another determinant of vaccination service users' satisfaction was their comfort at the health facility, including appropriate waiting rooms and waiting times not exceeding 25 minutes (10). According to these considerations, an independent waiting room reserved for vaccination service users could be an influential factor in the decision to get vaccinated, as would avoiding a burdensome wait time or the loss of working hours. Wait time could also be useful to provide people with information on vaccinations and to eliminate possible anxiety before their administration.

Moreover, the type of vaccination service staff can play a critical role in

vaccination service quality. According to the survey results, one healthcare worker (medical doctor or nurse) was available per 10,000 people. However, considering the average duration of 12 minutes required for each vaccination (17), fulfilment of a 15 vaccinations schedule according to the Italian vaccination plan (18), and the HCWs working hours according to Italian law, such a vaccination service staff seems to be really insufficient. Moreover, HCWs activity must be guaranteed homogeneously in all Italian Regions to achieve 95% coverage for both compulsory and recommended vaccinations.

According to the survey results, almost half of all vaccination service physicians were not specialized in public health. A lack of specialized university training in public health can make it more difficult to communicate about the topic of vaccination or to offer adequate support and counselling. This matter is bolstered by a study conducted in the United Kingdoms, where vaccination specialists needed to support HCWs (19). In particular, the advice of specialists was useful in answering questions related to users with an incomplete vaccination status, the vaccination of migrants, and vaccination safety. Additionally, in New Zealand, vaccination specialists had in-depth knowledge of the immunization topics (20). The main questions asked to specialists concerned changes in vaccination schedules and questions on immunization brought up by the media. A similar contribution could be offered by other HCWs as health assistants, not yet fully hired in the Italian National Health Service (21).

Moreover, the possibility of vaccinations at other health facilities (GP or paediatrician offices or pharmacies) would be useful in increasing vaccination coverage (22). Greater accessibility to vaccinations at the GP's or paediatrician's office would allow more people to be vaccinated, due to the higher frequency of visits to the GP or paediatrician and the public's greater trust in counselling from their GP or paediatrician (23-25). Moreover, enhancing the pharmacist's role, allowing the pharmacist to become more actively involved in the vaccination process, could lead to an increase in vaccination coverage, particularly among adults and the elderly and during influenza season, as has happened in other countries (26, 27).

Another area with a low level of compliance was the computerization of vaccination services. Only two-thirds of vaccination services were paperless and the only Region with completely computerized vaccination services did not run the same IT system in all offices. This low compliance level was already revealed in a previous study conducted in Italian Regions over 15 years ago (7, 8). The computerization of vaccination services is still a difficult objective for Italy, even though it can be a useful instrument for assessing and monitoring the accessibility, quality, and outcomes of immunization programmes. Electronic medical records (EMRs) can reduce public costs and improve information quality, shorten timelines, and increase the precision of the coverage data (28). EMRs can support the clinical decisions of physicians in vaccine administration and highlight potential risk factors, reduce missed opportunities, and increase the timeliness of vaccine administration.

The main limitation of the survey was the low number of returned questionnaires (35%) compared the total number of Italian Regions and Autonomous Provinces involved. This lack of response from so many Regions gives cause to wonder about the availability of much of the data requested. However, this survey constitutes a baseline of knowledge about Italian vaccination services, useful for decision makers in establishing certain minimum requirements to provide high-quality preventive healthcare services.

Conclusions

Improving the quality of Italian vaccination services can provide updated data to support actions to increase vaccination coverage, such as general invitations to the public, catch-up vaccination programmes, and the management of vaccine-hesitant individuals.

Riassunto

Come programmare, organizzare e gestire i servizi vaccinali? Risultati di un'indagine condotta sui servizi vaccinali italiani

Introduzione. Il miglioramento della qualità è riconosciuto come la strategia per massimizzare l'efficienza dei servizi e minimizzare i costi in Sanità Pubblica. La legislazione italiana però non prevede l'accreditamento istituzionale per i servizi vaccinali. In Italia, inoltre, è stata recentemente approvata la legge 119 del 2017 che rende obbligatorie ben 10 vaccinazioni dell'infanzia in luogo delle precedenti 4 e che ha determinato un incremento dell'impegno vaccinale. Questa legge però non si è basata su una preventiva valutazione delle risorse dei servizi vaccinali. L'obiettivo di questo studio è di descrivere le caratteristiche e l'adeguatezza dei servizi vaccinali italiani.

Disegno dello studio. È stata condotta un'indagine telematica, tra il settembre 2017 ed il settembre 2018, rivolta ai rappresentanti dei servizi vaccinali delle Regioni e delle Provincie autonome italiane.

Materiali e metodi. Il questionario on-line era costituito da 26 domande che indagavano le caratteristiche strutturali, organizzativi e gestionali dei servizi vaccinali. Le performances dei servizi vaccinali sono state valutate correlando il numero potenziale di utenti con le coperture vaccinali.

Risultati. Complessivamente 7 Regioni hanno aderito all'indagine, con una popolazione residente di oltre 15.000.000 abitanti. In media 519 bambini con età 0-2 anni afferivano potenzialmente ad ogni centro vaccinale, con un coefficiente di correlazione $\beta = -0.87$ ($p = 0.01$) con le coperture vaccinali dell'infanzia relative al 2016. L'85% dei servizi vaccinali ha riferito il completo abbattimento delle barriere architettoniche, ma un parcheggio riservato era presente solo nel 49% dei casi. In media vi erano 0,4 medici e 0,6 operatori sanitari per 10.000 abitanti ed il 74% dei servizi vaccinali era dotato di un'anagrafe informatizzata.

Conclusioni. Questo studio ha evidenziato come la minor afferenza per centro vaccinale sembri garantire una migliore copertura vaccinale, probabilmente per una maggiore accessibilità in senso lato. Questa indagine mostra una fotografia delle caratteristiche dei servizi vaccinali italiani che può risultare utile ai pianificatori per proporre standard di qualità.

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